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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte HANS SMOLA and GILBERTO NEPOMUCENO

Appeal 2010-002821
Application 10/596,159
Technology Center 1600

Before RICHARD M. LEOVITZ, FRANCISCO C. PRATS, and
STEPHEN WALSH, Administrative Patent Judges.

PRATS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims to a nutritional composition for promoting wound healing. The Examiner rejected the claims as obvious.

We have jurisdiction under 35 U.S.C. § 6(b). We affirm

STATEMENT OF THE CASE

Claims 1-5 stand rejected and appealed (App. Br. iii). Claim 1 is representative and reads as follows:

1. A nutritional composition for promoting wound healing comprising a protein source, a lipid source and a carbohydrate source, the composition comprising not more than 1.8% of the total calories of the composition as arginine and at least 3% of the total calories of the composition being proline.

The sole rejection before us for review is the Examiner's rejection of claims 1-5 under 35 U.S.C. § 103(a) as obvious over McEwen¹ and Gray² (Ans. 3-4).

DISCUSSION

ISSUE

The Examiner cited Gray as teaching a nutritional composition for enhancing wound healing, the composition containing proline at a caloric percentage between 4% and 6% (Ans. 3). The Examiner conceded, however, that Gray differed from the claimed composition in that Gray did not "teach the composition as comprising less than 1.8% of the total calories due[] to arginine" (id.).

To meet that feature the Examiner cited McEwen as disclosing nutritional formulations that contain arginine as about 1% of the total caloric content, and teaching that "arginine at such a caloric percentage is capable of accelerating wound healing and nitrogen retention after injury" (id. at 4).

Based on the references' combined teachings, the Examiner concluded that an ordinary artisan would have considered it obvious to prepare a composition containing lipid, protein, and carbohydrate, "wherein the composition comprises less than 1.8% of the caloric content is attributed

¹ U.S. Patent No. 6,194,379 B1 (filed May 1, 1998).

² U.S. Patent No. 5,714,472 (filed September 20, 1995).

to arginine. One would have been motivated to supplement the teaching of Gray with McEwen because the composition would accelerate the healing of wounds and aid in the retention of nitrogen” (id.).

Appellants contend that the Examiner failed to make a prima facie case of obviousness because Gray teaches away from using the amount of arginine used by McEwen, and also teaches away from the amount of arginine used in the wound healing compositions of the appealed claims (App. Br. ix-xii; see also Reply Br. 3-4, 6-7). Appellants also contend that Gray teaches away from McEwen with respect to the amount of proline to be used in wound healing compositions (App. Br. x, see also Reply Br. 5-6).

Appellants note that it is undesirable for elderly, bedridden, or critically ill patients to receive excessive arginine because arginine is a precursor for nitric oxide formation, which is highly likely to be deleterious to such patients, and that in light of this, the compositions of the appealed claims contain no more than 1.8% arginine on a total calorie basis (App. Br. ix, xi-xii; see also Reply Br. 2, 6). Thus, Appellants urge, Gray’s teaching of using more than 3% of total calories as arginine in its composition would have led an ordinary artisan on a path divergent from that taken by Appellants (App. Br. xii).

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

[T]he examiner bears the initial burden . . . of presenting a prima facie case of unpatentability. . . . After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

Appellants do not argue the claims subject to this rejection separately. We select claim 1 as representative of the rejected claims. See 37 C.F.R. § 41.37(c)(1)(vii).

Thus, in view of the positions advanced by Appellants and the Examiner, the issue in this rejection is whether a preponderance of the evidence supports a prima facie case that an ordinary artisan would have considered claim 1 obvious in view of Gray and McEwen.

FINDINGS AND ANALYSIS

Appellants' arguments do not persuade us that the Examiner failed to make a prima facie case that claim 1 would have been obvious to an ordinary artisan.

In *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), the Supreme Court reaffirmed that "when a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *Id.* at 417 (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273 (1976)).

The Court reasoned that:

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

Id. at 421.

Claim 1 recites a nutritional composition for promoting wound healing. The composition contains a protein source, a lipid source and a carbohydrate source.

Claim 1 specifies that no more than 1.8% of the total calories of the composition may be contributed by arginine. Claim 1 also specifies that at least 3% of the total calories of the composition are contributed by proline.

It is undisputed that both Gray and McEwen disclose nutritional compositions containing protein, lipid and carbohydrate sources, the compositions being administered to debilitated patients for the purpose of promoting healing. Thus, Gray discloses that “[p]roviding a high arginine, proline and/or cysteine content promotes wound healing and tissue repair/cell division” (Gray, col. 4, ll. 54-56).

Specifically, Gray discloses in one embodiment that “the proline content is at least 2.0% of the total calories” (id. at col. 6, l. 65). Gray also discloses that “[e]nhanced wound healing with arginine is believed to be provided at quantities greater than 3% of the total calories” (id. at col. 6, ll. 60-62).

While an ordinary artisan viewing Gray by itself might have considered claim 1’s maximum caloric percentage of 1.8% arginine not to have been suggested by Gray, McEwen teaches that 1% arginine is sufficient in wound healing compositions:

The protein system of the nutritional products of the present invention preferably includes L-arginine which provides a source of free amino acids. Desirably, the arginine will comprise about 1% of the total calories of the nutritional products. Arginine has several physiologic effects. The feeding of arginine has been shown to accelerate wound healing and nitrogen retention after injury. The effects on wound

healing may be due to increased synthesis of collagen in wounds. Published reports have indicated that rats fed diets supplemented with both arginine (24%) and glycine (1%) deposited more hydroxyproline, a component of collagen, in wounds that are healing when compared to animals fed control diets.

(McEwen, col. 9, ll. 1-13.)

Thus, the evidence as a whole supports the Examiner's determination that an ordinary artisan preparing a healing-promoting composition containing proline percentages suggested by Gray would have been prompted to include arginine as only 1% of the composition's total calories, in view of McEwen's teaching that that amount would be sufficient to promote wound healing in nutritional compositions. Accordingly, because the cited references show that claim 1 recites a wound healing nutritional composition that contains percentages of proline and arginine recognized in the art as being suitable in such compositions, we are not persuaded that the Examiner failed to make a prima facie case of obviousness.

Appellants' teaching away arguments do not persuade us that an ordinary artisan would have considered claim 1 unobvious. Specifically, Appellants' teaching away arguments require us to follow relevant teachings in one of the applied references, while ignoring relevant teachings in the other.

However, it is well settled that, "[n]on-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references. . . . [The reference] must be read, not in isolation, but for what it fairly teaches in combination with

the prior art as a whole.” In re Merck & Co., Inc., 800 F.2d 1091, 1097 (Fed. Cir. 1986).

Thus, Gray’s statement that “[e]nhanced wound healing with arginine is believed to be provided at quantities greater than 3% of the total calories” (Gray, col. 6, ll. 60-62 (emphasis added)) must be viewed in light of McEwen’s explicit teaching that arginine at only 1% of total calories is sufficient to achieve a wound-healing effect. Moreover, given the less than emphatic nature of Gray’s statement (see *id.*), we are not persuaded that an ordinary artisan viewing Gray in light of McEwen would have considered at least 3% arginine an absolute requirement, much less a teaching away. Similarly, the fact that McEwen might not suggest any particular proline requirement does not, in our view, amount to a teaching away from the proportions used in Gray.

Lastly, we acknowledge Appellants’ arguments that their purpose in using less than 1.8% of total calories was to minimize nitric oxide production in patients to which the claimed compositions are targeted (App. Br. ix, xi-xii; see also Reply Br. 2, 6). However, the fact that McEwen might suggest the claimed percentage of arginine for a different purpose does not render the claimed composition any less obvious. See KSR, 550 U.S. at 419 (“In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103.”)

In sum, a preponderance of the evidence supports the Examiner’s determination that an ordinary artisan would have considered claim 1 obvious in view of Gray and McEwen. As Appellants point to no secondary

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considerations of non-obviousness that come from the claimed composition,
we affirm the Examiner's rejection of claim 1 over those references.

Claims 2-5 fall with claim 1. See 37 C.F.R. § 41.37(c)(1)(vii).

TIME PERIOD

No time period for taking any subsequent action in connection with
this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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